

Self-expanding metallic stents as bridge to surgery in obstructing colorectal cancer

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Background: A self-expanding metallic stent (SEMS) may relieve intestinal obstruction to permit elective resection of colorectal cancer presenting as an emergency. There have been concerns regarding the oncological consequences of this strategy. This study evaluated outcomes in patients with potentially curable colorectal cancer treated with a SEMS as a bridge to surgery.

Methods: This retrospective study included patients with obstructing colorectal cancer in whom a SEMS procedure was attempted between January 2004 and August 2007. Palliative SEMS procedures were excluded. Outcomes for SEMS insertion and subsequent surgery were recorded with a focus on survival.

Results: SEMS insertion was attempted and achieved in 34 patients, of whom 30 were discharged after successful relief of obstruction. However, five patients needed acute surgery within 18 days owing to insufficient relief of obstruction (1), or tumour (3) or caecal (1) perforation, with one postoperative death. The remainder underwent elective surgery with no postoperative mortality. In all, 28 of 34 patients were stoma free after operation. The 3-year survival rate of all 34 patients was 74 (95 per cent confidence interval 53 to 86) per cent after a median follow-up of 33.7 months. A curative outcome was achieved in 30 patients.

Conclusion: Although associated with significant short-term problems, a SEMS can be useful in converting an emergency into an elective situation. No adverse oncological consequences were identified.

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Introduction

Some 14 per cent of patients with colorectal cancer present acutely as a surgical emergency¹. The main indications for emergency surgery are large bowel obstruction, perforation or bleeding. These patients have a poor outcome as morbidity and postoperative mortality rates are higher¹, rates of resection and curative resection are lower, and long-term survival is poorer than in patients admitted electively^{2,3}.

Since the introduction of self-expanding metallic stent (SEMS) devices in the 1990s, some patients with bowel obstruction presenting as an emergency have been treated with a SEMS to restore luminal patency. The SEMS option enables accurate tumour staging afterwards. In some patients with disseminated or incurable disease SEMS insertion may serve as definitive palliative treatment. In patients with potentially curable colorectal cancer, however, use of a SEMS allows elective surgery with presumed

better morbidity and mortality. The volume depletion and metabolic derangement seen in patients with acute bowel obstruction may be optimized by a SEMS combined with fluid, electrolyte and nutritional restitution. The stent also provides the opportunity to administer neoadjuvant therapy (when needed) to improve oncological outcomes.

Several publications have reported a favourable outcome after SEMS insertion in obstructing colorectal cancer, although most studied only the success rate, technical performance and short-term outcome⁴⁻⁶. At least subclinical perforations may occur during the insertion procedure and it has been demonstrated that SEMS insertion may lead to tumour cells in the peripheral circulation⁷. For patients who have a SEMS as a bridge to surgery, the (edges of the) stent may be visible during the scheduled operation because of a previous subclinical tumour perforation. The impact of such events on long-term outcome is unknown. To date, there are only two small reports on long-term survival after insertion of a SEMS as a bridge to surgery

in patients with obstructing potentially curable colorectal cancer^{8,9}. Randomized controlled trials comparing the efficacy of SEMS insertion *versus* immediate surgery for obstructing colorectal cancer are ongoing^{10,11}.

The aim of this study was to evaluate the clinical success and long-term survival of SEMS insertion as a bridge to surgery in consecutive patients with potentially curable colorectal cancer presenting with acute obstruction. Specific aims were to study the success rate of SEMS insertion, to evaluate the short-term clinical outcome including the need for reintervention, and to determine the cumulative 30-day mortality rate and overall survival.

Methods

The study base comprised all patients with colorectal cancer who had a SEMS insertion procedure for acute bowel obstruction in the Department of Surgery P, Aarhus University Hospital, between January 2004 and August 2007. Only patients with potentially curable colorectal cancer were included in this retrospective analysis, that is patients suitable for surgery and without distant metastases.

The department is a primary and tertiary referral centre for patients with acute and elective colorectal diseases. The primary admission area covers approximately 350 000 inhabitants for elective admissions and 450 000 inhabitants for acute admissions. Traditionally the majority of colorectal endoscopic procedures are performed by surgeons. According to departmental policy, all acute colorectal operations, and most SEMS attempts, are performed or supervised by colorectal surgeons. SEMS insertion was introduced in the department during 2003. The treatment strategy for patients with acute bowel obstruction located anal to the right flexure was SEMS insertion in all patients without signs of perforation. Such patients would otherwise have undergone acute surgery. Bowel obstruction was not defined exactly, but included a combination of lack of passage of flatus and faeces, abdominal pain and dilated bowel on computed tomography (CT). After SEMS insertion, patients with potentially curable colorectal cancer were offered an elective resection. Colorectal cancer was diagnosed by endoscopy and verified histologically, and distant metastases were ruled out by CT of the thorax and abdomen.

Theatre procedure lists (daily listings of all elective, acute and attempted procedures performed in the operating theatre) were reviewed to identify all potentially eligible SEMS procedures: endoscopic examinations (sigmoidoscopy with or without SEMS insertion; colonoscopy with or without SEMS insertion) and all acute colonic operations (unplanned) to ensure that failed SEMS insertions

were also included. The vast majority of the procedures were diagnostic endoscopic examinations to investigate bleeding, anaemia, etc. All patients registered in the theatre procedure list as potentially eligible for a SEMS were searched in the Patient Administrative System (PAS) to check whether the procedure note for that specific date recorded an attempt at SEMS insertion. The medical records of all patients in whom SEMS insertion had been performed or attempted were reviewed.

Stent placement

All SEMS insertions were performed in the operating theatre and carried out under general anaesthesia or conscious sedation. Patients were placed in the supine position. Stents were placed using a combination of direct endoscopic visualization and fluoroscopy. Stents used were enteral WallstentTM (Microinvasive Endoscopy, Boston Scientific, Natick, Massachusetts, USA), WallflexTM colonic stent (Microinvasive Endoscopy) and Niti-STM colorectal stent (Taewoong Medical, Seoul, Korea). All patients underwent plain abdominal X-ray after SEMS insertion to document the stent position. Predilatation was never performed.

Data from medical records

The following data were retrieved: patient demographics, American Society of Anesthesiologists score, indication for SEMS placement, site of obstruction, technical and clinical success of SEMS insertion, grade of surgeon who inserted the stent, preoperative and postoperative radiological examinations, postoperative complications including perforation and reintervention, length of hospital stay, acute (performed within 24 h) and elective (scheduled) operations, and final oncological outcome (curative or palliative).

Data sources

Before reviewing the medical record, the PAS was used to check whether the procedure note recorded that SEMS insertion had been attempted. The PAS is a regional registry that was established in 1977. It includes information registered under the patient's personal identification number (a unique ten-digit identifier assigned to all Danish residents by the Central Office of Civil Registration since 1968), and is used to collect information for the National Registry of Patients on the activities of hospitals, for example surgical procedure(s) performed (coding done by surgeons) and up to 20 discharge diagnoses (coding by physicians). The validity of data from the registries is high^{12,13}. Dates of death were retrieved from the Central

Office of Civil Registration. All study patients were followed until death or 1 December 2009, whichever came first.

Outcome measures

Technical success was defined as accurate SEMS placement with adequate stricture coverage. Clinical success was defined as decompression and relief of obstructive symptoms without further interventions during the hospital stay. Perforation was diagnosed at surgery, by radiological examination or at autopsy. Bridge to surgery was defined as scheduled elective surgery, independent of the time between SEMS insertion and surgery.

Cumulative 30-day mortality after SEMS insertion and bridge to surgery was based on deaths within 30 days after SEMS placement and bridge to surgery respectively. Cumulative 30-day mortality was calculated on an intention-to-treat (ITT) basis, regardless of the technical and clinical success of the SEMS attempt; it included deaths within 30 days after failed and successful SEMS attempts, acute surgery performed during the wait for scheduled elective surgery, and scheduled elective surgery. Similarly, survival after SEMS placement as a bridge to surgery was calculated in ITT analysis independently of the success of SEMS insertion and the timing of surgery.

Statistical analysis

Continuous variables were presented as median (range). Survival estimates, with 95 per cent confidence intervals, were calculated by the Kaplan–Meier method. Statistical calculations were performed with the use of SPSS® version 8.0.2 (SPSS, Chicago, Illinois, USA).

Results

The operation notes of 1835 patients potentially eligible for SEMS insertion were reviewed, and 80 patients with colorectal cancer in whom acute SEMS insertion had been attempted because of acute bowel obstruction were identified. The study included 34 patients with potentially curable colorectal cancer (*Table 1*). The remaining 46 patients did not fulfil the eligibility criteria: 24 had distant metastases detected before or after the SEMS attempt, 12 were unfit for surgery because of severe co-morbidity or advanced age, and ten patients were transferred to their primary hospital for definitive evaluation and treatment.

Technical success rate of stent insertion

Successful SEMS insertion was achieved in all 34 patients (technical success rate 100 per cent). Thirty-one of the 34

Table 1 Characteristics of 34 patients who had stent insertion for bowel obstruction from colorectal cancer

	No. of patients*
Age (years)†	73 (42–94)
Sex ratio (M:F)	16:18
ASA grade	
I	4
II	12
III	3
Unknown	15
Site of tumour	
Transverse colon	6
Splenic flexure	5
Descending/sigmoid colon	23
Preoperative abdominal CT/X-ray	
No	1
Yes	33
Contrast enema (X-ray)	
No	16
Yes	18
Caecal diameter (cm)‡	9.3 (6.0–15.0)
SEMS insertion	
Performed or supervised by a colorectal surgeon	31 (91.2)
Duration of procedure (min)†	35 (20–110)
No. of stents used	
1	33
2	1
Type of SEMS	
Enteral Wallstent™	11
Niti-S™ colorectal stent	4
Wallflex™ colonic stent	6
Unknown	13
Technically successful procedure	34
Duration of hospital stay (days)†§	3 (2–23)

*Unless indicated otherwise; †values are median (range). ‡Data not available for nine patients. §Excluding seven patients who underwent surgery during the initial hospital stay. ASA, American Society of Anesthesiologists; CT, computed tomography; SEMS, self-expanding metallic stent.

attempted stent insertions were performed or supervised by a colorectal surgeon. Further technical information on the SEMS procedures is summarized in *Table 1*.

Clinical success rate and interventions before elective surgery

Four patients had events that categorized the procedure as a clinical failure (clinical success rate 88 per cent). One patient with insufficient relief of obstructive symptoms underwent an unsuccessful attempt at a further SEMS procedure 9 days following the primary insertion, but acute surgery was needed. Two patients had tumour perforation and underwent acute surgery, one on the same day as SEMS insertion and the other 5 days after SEMS placement. One patient presented as an abdominal emergency 3 days after stent insertion and a blow-out perforation in

the caecum was identified at acute laparotomy. Clinical failure occurred equally in patients with tumours located in the transverse colon or splenic flexure (1 of 11) and descending/sigmoid colon (3 of 23).

Three patients had a scheduled elective resection during the hospital stay and were classified as having a bridge to elective surgery (see below). Thus, 27 patients had a functioning SEMS in place at the time of discharge from hospital or death; their median hospital stay was 3 days (*Table 1*).

After discharge, two patients needed surgical re-intervention while awaiting elective resection. One experienced SEMS migration and underwent successful stent reinsertion followed by an elective resection. Another developed tumour perforation 18 days after SEMS insertion and had acute surgery. The overall perforation rate was 12 per cent (4 of 34). The perforation rate was comparable for tumours located in the transverse colon or splenic flexure (1 of 11) and descending/sigmoid colon (3 of 23).

A total of five patients had acute surgery after SEMS insertion; their details and outcome are summarized in *Tables 2* and *3*. After operation, one patient received antibiotics and supportive care in the intensive care unit for peritonitis and sepsis, but died within 30 days. Two further

Table 2 Characteristics and operative data of patients who had elective colorectal surgery and those who had acute surgery after stent insertion for bowel obstruction

	Elective bridge to surgery (n = 29)	Acute unplanned surgery (n = 5)
Age (years)*	73 (42–94)	73 (51–84)
Sex ratio	14:15	2:3
Type of surgery		
Extended right hemicolectomy	1†	1‡
Transverse colectomy	4	0
Left hemicolectomy	9	0
Sigmoid colectomy	11	0
Hartmann's resection	2§	1
Total colectomy + IRA	1	1
Total colectomy + stoma	1¶	2
Status of SEMS at time of surgery		
In place, no abnormalities	20	2#
SEMS penetrated through bowel wall	1**	3
Omentum adherent to tumour	6	0
SEMS not in place	2	0

*Values are median (range). †Tumour located in oral part of transverse colon. ‡Including transverse resection (tumour located in anal part of transverse colon and right colon dilated). §One patient had a locally advanced tumour involving the left adnexa and pelvic cavity; the other was 85 years old and had severe co-morbidity. ¶The patient had undergone a Hartmann's procedure for rectal cancer 6 years previously. #One had a caecal perforation. **Omentum adherent to the tumour and self-expanding metallic stent (SEMS). IRA, ileorectal anastomosis.

Table 3 Outcome data for patients who had elective colorectal surgery and those who had acute surgery after stent insertion for bowel obstruction

	Elective bridge to surgery (n = 29)	Acute unplanned surgery (n = 5)
Hospital stay after SEMS insertion (days)*	4 (2–23)‡	3§
Interval from SEMS insertion to surgery (days)*	35 (6–100)	6 (0–18)
Hospital stay after surgery (days)*	7 (3–16)	11 (8–32)
Postoperative complications	3	3
Deaths within 30 days	0	1
Colorectal cancer pathological stage ¹⁴		
Tumour category		
pT3	15	3
pT4	14	2
Node category		
pN0	14	3
pN1	8	1
pN2	7	1
Follow-up (months)*	34.7 (9.8–70.5)	32.0 (0.3–52.3)
Curative outcome	25	5
Survival after SEMS insertion (years)†	5.0 (3.3, 6.6)	4.3 (0.5, 4.8)

*Values are median (range) and †median (95 per cent confidence interval). ‡Twenty-six patients. §Only one patient was discharged after self-expanding metallic stent (SEMS) insertion; the remaining four underwent surgery during the initial hospital stay.

patients had postoperative complications from which they recovered; one received antibiotics for prolonged fever, and one had a prolonged recovery because of poor general condition.

Elective bridge to surgery

In total, 29 patients had an elective resection including the three patients who stayed in hospital until scheduled surgery; their characteristics are shown in *Tables 2* and *3*. Elective surgery was performed a median of 35 (range 6–100) days after SEMS insertion. One patient waited 100 days because diabetes and severe heart disease diagnosed after SEMS insertion had to be stabilized before surgery. None of these 29 patients died within 30 days after surgery. Three developed postoperative complications; one had a wound infection that required opening and two had a urinary tract infection.

Cumulative 30-day mortality

The overall 30-day mortality rate after technically successful SEMS placement was zero. Of five patients who had

acute surgery, the one with a blow-out perforation died 7 days later secondary to peritonitis. Thus, the cumulative 30-day mortality rate after SEMS insertion and surgery was 3 per cent (1 of 34).

Outcome

Twenty-eight of 34 patients were stoma free after surgery.

Two- and 3-year survival rates for the 34 patients with potentially curable colorectal cancer were 85 (68 to 94) and 74 (53 to 86) per cent respectively after a median follow-up of 33.7 months independent of oncological outcome and timing of surgery. Median survival was 4.5 (3.1 to 6.0) years.

A curative outcome was achieved in 30 patients (88 per cent) who had no evidence of distant metastases and underwent radical resection. Half of the patients had stage III cancer. Two- and 3-year survival rates after surgery with curative outcome were 90 (72 to 97) and 77 (54 to 89) per cent.

After SEMS insertion, liver metastases that were deemed potentially curable by the liver multidisciplinary team were detected in three patients. However, curative liver resection was possible in only one of these patients because the liver metastases proved incurable at time of liver surgery in the second patient and the third also had peritoneal carcinomatosis. Two other patients had a palliative outcome; both had incurable peritoneal carcinomatosis detected at the time of bowel resection (30 days after SEMS placement).

Discussion

The long-term benefit of SEMS insertion as a bridge to surgery has been questioned recently because of the potential danger of tumour seeding in patients with acute bowel obstruction treated by stenting. In the present study, despite perforation in 12 per cent after SEMS insertion, the 3-year survival rate of patients with potentially curable colorectal cancer was 74 per cent after a median follow-up of almost 3 years, regardless of the outcome and timing of surgery.

The technical success rate of 100 per cent may be explained by the fact that only patients with potentially curable lesions were included. The clinical success rate of 88 per cent was similar to that in previous studies⁴⁻⁶. The main cause of clinical failure was SEMS-related perforation, which occurred at more than twice the rate reported previously⁴⁻⁶. The four perforations occurred 0, 3, 5 and 18 days after SEMS insertion, and three were tumour perforations. Tumour perforation is a main oncological concern regarding the use of these stents. Recently,

some authors have warned about late perforations in patients treated with a SEMS as palliation while receiving chemotherapy^{15,16}. However, none of the present patients was receiving systemic chemotherapy, tumour location had no obvious influence and there was no clear reason for the high perforation rate.

Instead of 30-day mortality, it was deemed more appropriate to calculate the cumulative 30-day mortality rate (deaths after SEMS insertion and following either acute or elective surgery). This cumulative rate was only 3 per cent, although there may have been bias because of the longer observation time. The Danish 30-day mortality rate after emergency surgery for obstructing colonic cancer is 21 per cent¹, and other countries have similarly reported high mortality rates¹⁷⁻¹⁹. Obviously, the mortality rate of 3 per cent after SEMS placement followed by surgery and that of 21 per cent after emergency surgery for obstructive colorectal cancer are not fully comparable as the latter may also include patients with concomitant perforation (and a higher mortality risk). Nevertheless, in the short term, the SEMS approach has obvious life-saving advantages in patients with acute bowel obstruction.

Thirty patients (88 per cent) had a curative outcome even though five required emergency surgery. A curative outcome is obtained less frequently in patients undergoing emergency resection of colorectal cancer^{2,3}. The authors' stringent departmental policy that all acute colonic surgery should be supervised by a colorectal surgeon may have contributed to the high rate of curative treatment. The 3-year survival rate after emergency colonic cancer surgery for patients with a curative outcome was 50 per cent in 2001-2005 according to data from the Danish national colorectal cancer database²⁰. However, this rate may be subject to selection bias because some hospitals in Denmark implemented the SEMS modality at the beginning of the 2000s. In the present study, patients having SEMS insertion as a bridge to surgery with curative outcome had a 3-year survival rate of 77 per cent, that is 27 per cent higher in absolute figures, even though half of the patients had stage III disease and almost a sixth needed acute surgery. With tailored patient management allowed by the SEMS modality, the 3-year survival rate after curative surgery was comparable to that of 75 per cent after elective curative surgery for colonic cancer in Denmark²⁰. Therefore, this study failed to demonstrate a deleterious effect of SEMS insertion for acute bowel obstruction on the long-term prognosis of patients with potentially curable colorectal cancer; instead it provided evidence that SEMS placement is associated with favourable long-term survival.

Few studies have evaluated the effect of SEMS insertion compared with emergency surgery on long-term prognosis in patients with potentially curable colorectal cancer. A Japanese abstract reported no difference in 3-year survival between 44 patients treated with SEMS insertion followed by resection and 40 patients who had emergency surgery (48 *versus* 50 per cent)²¹. An English study noted a 3-year survival rate of 80 per cent in ten patients who had SEMS insertion as a bridge to potentially curative resection compared with 74 per cent in 15 patients who underwent emergency resection, after a mean follow-up of 21 months⁹. In a recent Korean study, the 5-year survival rate was 44 per cent in 24 patients with stage II and III colonic cancer after SEMS placement as a bridge to surgery *versus* 87 per cent in 240 patients who had elective surgery for non-obstructing left-sided colonic cancer⁸.

Survival rates in the English study⁹ and in the present series are higher than those in the other two published series^{8,21}. Besides different methods of analysis (ITT or not), there are differences in the time from SEMS insertion to elective surgery. In most studies the median interval was 5–6 days⁶, whereas it was 35 days in the present series and 70 days in the English study⁹. A long interval was used in the present study for logistical reasons (allowing time for preoperative evaluation and staging, space on operating lists), and to allow the patient to recover from bowel obstruction and the bowel to decompress sufficiently. In addition, there is no evidence that a long hospital delay adversely affects long-term survival of patients with colonic cancer²². However, one of the present patients could have been spared acute surgery for perforation had elective surgery been offered 5–6 days after SEMS insertion.

Although efforts were made to minimize weaknesses caused by a retrospective study design, it cannot be ruled out that some minor complications may have been missed. The type of SEMS used was unknown for a third of the procedures. There was some disparity in perforation rate between different types of stent (two perforations among four Niti-STM stents and two among 11 WallstentTM devices), which may be a coincidence.

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Commentary

Self-expanding metallic stents as bridge to surgery in obstructing colorectal cancer (*Br J Surg* 2011; **98**: 275–281)

Up to 25 per cent of patients with colonic cancer present with acute obstruction. These patients experience higher mortality and morbidity rates than patients without obstruction, including an increased risk of prolonged hospital stay, stoma formation and compromised oncological outcome¹. The concept of colonic stenting as a means of avoiding emergency surgery by non-operative colonic decompression is, therefore, an interesting primary interventional option that may improve outcome. The concept embraces palliative situations and, as in the present study, potentially curable cancer. High technical and short-term clinical success rates are reported, although mostly from small-volume series².

Promising results in regard to curative outcome and long-term survival are described in the present selected patient series. The tumours were located oral to, in or distal to the splenic flexure and different types of stent were used. The median time from stent insertion to surgery seems long with a wide range of up to 100 days. These variations make interpretation of outcome somewhat challenging.

A concern is tumour perforation that may or may not be acknowledged and that can cause tumour cell dissemination³. The present study addresses this important oncological issue, although in a small and retrospective patient series. The risk of perforation should be further addressed through prospective trials focusing on potential adverse long-term oncological consequences. Survival, including the use of adjuvant therapy and tumour recurrence, should be specified as should methods for detection of perforation. Until the results from randomized studies come to maturity, concern about the tumour perforation rate should not be neglected.

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